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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,373	12/29/2000	Donald L. Morton	JWCI:011USC1	8298

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EXAMINER	
SALIMI, ALI REZA	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 02/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/751,373	MORTON, DONALD L.	
	Examiner	Art Unit	
	A R Salimi	1648	

-- Th MAILING DATE of this communication app ars on the cov r sheet with th correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-20 and 32-36* is/are pending in the application.

4a) Of the above claim(s) *11-17 and 34-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7-10,18-20,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 January 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/27/2001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1648.

Response to Amendment

This is a response to the amendment filed 1/26/2004. Claims 2-6, 21-31 have been canceled. Claims 32-36 have been added. Claims 1, 7-20, 32-36 are presently pending in the application.

Election/Restrictions

Applicant's election with traverse of Group III (claims 1, 7-10, 18-20, 32, and 33) in Paper filed 1/26/2004 is acknowledged. The traversal is on the ground(s) that search and examination of the species would not be unduly burdensome, because if the broad claim 1 is found allowable then additional limitations will not even come into play. This is not found persuasive because first the presumption is that broad claim 1 is allowable which has no bearing on whether or not examination of other distinct groups are burdensome or not. Second, as it was clearly stated the separate classification(s) of the subject matter is/are prima facie showing of burden, which is not overcome by applicant's assertion to the contrary.

Claims 11-17, 34-36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups, the requirement having been traversed in Paper No. 10.

Applicant is reminded to cancel the claims to the non-elected claims.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. Please also include the patent number.

Claim Rejections - 35 USC § 112

Claims 1, 7-10, 18-20, 32, 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite the intended metes and bounds of the composition is not defined. It is not clear. What are the intended "four common allotypes"? The intended "antigens" are not defined? In addition, for a "composition comprising" there has to be more than one element present. What is in the composition beside the "antigen"? Is a pharmaceutical carrier intended? This affects the dependent claims.

Claim 7 is vague and indefinite, the intended "antigens" and "or other alloantigens by polymorphic genes" is/are not defined. It is difficult to ascertain the intended boundaries of the claimed invention, because the specification does not set forth clear boundaries as what is and isn't intended.

Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 8 in line two refers to "all known allotypes", the parent claim 1 is directed to "four common allotypes." All Known allotypes is broader than the common four. In addition, the claim is indefinite for recitation of "all known allotypes", what the "all known allotypes"?

Claim 10 is vague and indefinite and incomprehensible for recitation of "following human allotypes", but no allotypes have been recited in the presently claim version provided. The insertion of information is requested.

Claim Rejections - 35 USC § 101

Claims 1, 7-10 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1, 7-10, as written, do not sufficiently distinguish over nucleic acids, proteins, cells as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified."

Claim Rejections - 35 USC § 112

Claims 1, 7-10, 18-20, 32, 33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant disclosure, the Applicant has only disclosed a general method of generating an anti-major histocompatibility complex (MHC) immune response. However, the disclosure does not provide for a specific product isolated from a mammal in general or human in particular that can be administered to a suitable host. No sequences which "comprise, comprises, or comprising" are disclosed. The specification does not set forth the metes and bounds of MHC antigens from all allotypes, polymorphic genes, etc.... There is not enough information about it in literature either to guide the one of ordinary skill in the art to predict the undisclosed "antigens." Therefore, a written description of the "antigens" should be disclosed to overcome this rejection. See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. 35 USC 112 requires inter alia that a patent specification contain a written description of the invention and the manner and process of making and using it "in such full clear and concise terms as to enable one skilled in the art ... to make and use" the invention. Case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification

contains sufficient information to enable a skilled chemist to produce a particular compound because it gives detailed information on how to produce analogous compounds but it makes no reference to the compound in question, the "written description" requirement has not been met even though the description may be enabling. See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997):

> The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA .... Accordingly, the specification does not provide a written description of the invention ....

and at pg 1406:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

> A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials .... Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by it principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7-10, 18-20, 32, 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Urban et al (WO 94/04171).

The product disclosed in the above cited reference appears to be identical or so similar that is indistinguishable from the product claimed by the applicants (see the abstract, and claims 1-15). Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Hence, the disclosure of the above cited reference anticipates the claimed invention. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claims 1, 7-10, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Stott et al (WO 93/14126).

The product disclosed in the above cited reference appears to be identical or so similar that is indistinguishable from the product claimed by the applicants (see the abstract, and claims 1-8). Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Hence, the disclosure of the above cited reference anticipates the claimed invention. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claims 1, 7-10, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Irie et al (US patent No. 4,557,931).

The product disclosed in the above cited reference appears to be identical or so similar that is indistinguishable from the product claimed by the applicants (see claims 1-4). Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Hence, the disclosure of the above cited reference anticipates the claimed invention. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 7-10, 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Pietropaolo et al (US Patent No. 5,891,437).

The product disclosed in the above cited reference appears to be identical or so similar that is indistinguishable from the product claimed by the applicants (see claims 1-16). Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Hence, the disclosure of the above cited reference anticipates the claimed invention. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claims 1, 7-10, 18-20, 32, 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Ravindranath et al (US Patent No. 6,218,166 B1).

The product disclosed in the above cited reference appears to be identical or so similar that is indistinguishable from the product claimed by the applicants (see the abstract, and claims 1-30). Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Hence, the disclosure of the above cited reference anticipates the claimed invention. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The Official fax number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A. R. Salimi
2/18/2004